

DETAILED ACTION

Acknowledgement is made of the amendment filed 6/15/2011, amending claims 1 and 17 and canceling claim 5. Accordingly, claims 1-4 and 6-25 are currently pending and presented for examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 17 and 25** are rejected under 35 U.S.C. 102(b) as being anticipated by **Mauze et al. (US 6,210,420)**.

Regarding claims 1, 17 and 25, Mauze discloses a lancing device comprising: a needle (194); a moving member (178, which includes rod 182 and resilient support 204, as they all move together) for moving the needle in an advancing direction from a standby position to a puncturing position, the needle being attached to the moving member (figs. 7-8); and a housing (172, 174) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (202) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (184,190) which is

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offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 4, lines 25-41; columns 5-6, lines 66-67, 1-22). Mauze also discloses a dividing wall (179) for dividing the first inner space (184, 190) of the housing and the second space ((202); figs. 7-8); wherein the dividing wall (179) is connected between the moving member (178) and the housing ((172, 174); figs. 7, 8). The moving member (178, 182, 204) includes a rear end (204) and a front end (178) opposite to the rear end, the rear end being located within the first space (202), the front end being located within the second space ((184, 190); figs. 7-8).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-4 and 6-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sato et al. (US 7,131,984 B2)** in view of **Mauze et al. (US 6,210,420)**.

Regarding claims 1 and 23, Sato et al. disclose a lancing device comprising: a moving member (32) for moving a needle in an advancing direction from a standby position to a puncturing position; and a housing (2) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (30) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (21) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 7, lines 4-22). Sato et al. disclose a latch (15) for holding the moving member at the standby position (fig. 1). Sato et al. disclose wherein the moving member includes a rear end and a front end opposite to the rear end, the rear end being located within the first space, the front end being located within the second space (fig. 5; wherein one end of plunger 32 is open to chamber 30 when valve 33B is open and the opposite end of plunger 32 is open to chamber 21 via passage 60).

Sato et al. fail to disclose wherein the needle is attached to the moving member.

However, Mauze teaches a lancing device comprising: a needle (124 or 194); a moving member (128 or 178) for moving the needle in an advancing direction from a standby position to a puncturing position, the needle being attached to the moving

member (figs. 1, 7-8); and a housing (106, 104 or 172) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (156 or 184, 190) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (fig. 1 or 202) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 4, lines 25-41; columns 5-6, lines 66-67, 1-22). Mauze also discloses a dividing wall (179) for dividing the first inner space (184, 190) of the housing and the second space ((202); figs. 7-8); wherein the dividing wall (179) is connected between the moving member (178) and the housing ((172, 174); figs. 7, 8).

Given the teachings of Mauze, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sato et al. with the moving member and the needle attached to one another. Doing so would reduce the overall size of the lancet device, making it more convenient to handle.

Regarding claim 2, Sato et al. essentially disclose the lancing device according to claim 1, further comprising a fixing means (31a) for fixing the moving member to the housing at the standby position, with an urging force applied in the advancing direction, and also comprising a disengaging means (4) for dissolving the fixing of the moving

member, wherein the moving member is moved from the standby position in the advancing direction by the urging force (column 6, lines 56-61).

Regarding claim 3, Sato et al. essentially disclose the lancing device according to claim 2, wherein the urging force is applied to the moving member by a resilient member ((34); columns 6-7, lines 62-67, 1-3).

Regarding claim 4, Sato et al. essentially disclose the lancing device according to claim 3, wherein the resilient member is a coil spring (34, 17a, 17b) or a bellows (column 7, lines 66-67).

Regarding claim 6, Sato et al. essentially disclose the lancing device according to claim 5, wherein the moving member (31) is moved in the retreating direction (N2) by making pressure in the first space (30) smaller than pressure in the second space (21) beyond a predetermined value (column 8, lines 53-60).

Regarding claim 7, Sato et al. essentially disclose the lancing device according to claim 6, wherein the moving member is moved in the retreating direction by making pressure in the first space smaller than atmospheric pressure beyond a predetermined value (column 9, lines 6-16).

Regarding claim 8, Sato et al. essentially disclose the lancing device according to claim 5, further comprising a negative pressure generating means for generating a negative pressure in the second space (column 9, lines 6-16).

Regarding claim 9, Sato et al. essentially disclose the lancing device according to claim 8, wherein the negative pressure generating means individually generates

negative pressure in the first space and the second space (columns 8-9, lines 53-67, 1-16).

Regarding claim 10, Sato et al. essentially disclose the lancing device according to claim 8, wherein the negative pressure generating means generates the negative pressure in the first space for applying a suctioning force to the moving member, so that the moving member is moved to the standby position (columns 8-9, lines 53-67, 1-16).

Regarding claim 11, Sato et al. essentially disclose the lancing device according to claim 8, wherein the negative pressure generating means comprises a pump (3).

Regarding claim 12, Sato et al. essentially disclose the lancing device according to claim 2, wherein air flow into the first space (30) is caused before or on disengaging the moving member (31) by the disengaging means ((4); column 8, lines 54-64).

Regarding claim 13, Sato et al. essentially disclose the lancing device according to claim 12, wherein the air flow into the first space is caused when the moving member is disengaged by the disengaging means (column 8, lines 54-64).

Regarding claim 14, Sato et al. essentially disclose the lancing device according to claim 13, wherein the disengaging means (4) comprises an operating portion (5) to be operated to cause the disengaging means to act on the engaging means, wherein positional selection of the operating portion determines whether the first space (30) is caused to communicate with outside or not to communicate with the outside (column 9, lines 30-37).

Regarding claim 15, Sato et al. essentially disclose the lancing device according to claim 14, wherein the operating portion (5) is movable in the advancing direction and

the retreating direction, with part thereof protruding out of the housing, the operating portion including an engaging part (52) accommodated in the housing, wherein the housing is formed with a through-hole (55) for allowing the operating portion to move in the advancing direction and in the retreating direction, wherein the engaging part is used to select between a state in which the engaging part closes the through-hole and a state in which the engaging part does not close the through-hole (column 8, lines 20-24).

Regarding claim 16, Sato et al. essentially disclose the lancing device according to claim 1, wherein the second space (21) is provided with a retreating means (13) for moving the needle back in the retreating direction after the needle is brought to the puncturing position (column 7, lines 23-41; fig. 1).

Regarding claims 17, 24 and 25, Sato et al. disclose a lancing device comprising: a moving member (31) for moving a needle (10b) in an advancing direction from a standby position to a puncturing position; and a housing (2) allowing the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction, wherein a dividing wall is provided for dividing an inner space of the housing into a first space (30) offset in the retreating direction and a second space (21) offset in the advancing direction (column 7, lines 65-67; wherein a bellow is defined by a dividing wall and the spring may be replaced with a bellow), wherein the moving member (31) is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space

(abstract; columns 8-9, lines 53-67, 1-16). Sato et al. disclose a latch (15) for holding the moving member at the standby position (fig. 1).

Sato et al. fail to disclose wherein the needle is attached to the moving member.

However, Mauze teaches a lancing device comprising: a needle (124 or 194); a moving member (128 or 178) for moving the needle in an advancing direction from a standby position to a puncturing position, the needle being attached to the moving member (figs. 1, 7-8); and a housing (106, 104 or 172) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (156 or 184, 190) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (fig. 1 or 202) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 4, lines 25-41; columns 5-6, lines 66-67, 1-22). Mauze also discloses a dividing wall (179) for dividing the first inner space (184, 190) of the housing and the second space ((202); figs. 7-8); wherein the dividing wall (179) is connected between the moving member (178) and the housing ((172, 174); figs. 7, 8).

Given the teachings of Mauze, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sato et al. with the moving

member and the needle attached to one another. Doing so would reduce the overall size of the lancet device, making it more convenient to handle.

Regarding claim 18, Sato et al. essentially disclose the lancing device according to claim 17, wherein the dividing wall includes a bellows (column 7, lines 65-67).

Regarding claim 19, Sato et al. essentially disclose the lancing device according to claim 18, further comprising a fixing means (31a) for fixing the moving member (31) to the housing (2) at the standby position, with an urging force applied in the advancing direction, wherein the moving member is moved from the standby position in the advancing direction by the urging force (column 6, lines 56-61).

Regarding claim 20, Sato et al. essentially disclose the lancing device according to claim 19, wherein the urging force is applied to the moving member by at least one resilient member (34, 17a, 17b).

Regarding claim 21, Sato et al. essentially disclose the lancing device according to claim 20, wherein said at least one resilient member comprises the bellows (column 7, lines 65-67).

Regarding claim 22, Sato et al. essentially disclose the lancing device according to claim 21, wherein said at least one resilient member further comprises a coil spring ((34, 17a, 17b); column 7, lines 65-67).

Response to Arguments

Applicant's arguments with respect to claims 1-4 and 6-25 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed with respect to Figures 7 and 8 of Mauze have been fully considered but they are not persuasive. The applicant argues that Mauze fails to disclose the rear end being located in the first space. However, as discussed above, the examiner interprets resilient member 204 to be a part of the moving member, as resilient member 204, rod 182 and piston 178 all move together simultaneously as one piece. Accordingly, the rear end 204 of the moving member is in fact in the first space.

With respect to applicant's arguments in view of Sato, although a new rejection has been made, the examiner notes that the needle 10 of Sato is operatively attached to the moving member 32, via plunger 1. As shown in Figure 5 of Sato, plunger 32 connects to plunger 1, which carries needle 10.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH SIMPSON whose telephone number is (571)270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, *please contact* the examiner's supervisor, Tom Hughes, at (571) 272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

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/SAS/

Examiner, Art Unit 3731

8/29/2011

/Ryan J Severson/

Primary Examiner, Art Unit 3731

8/29/11